

May 11, 2004

Dockets Management Branch  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

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1300 Pennsylvania Avenue, N.W.  
Room 52C  
Washington, D.C. 20229

Re: Docket No. 02N-0278 – Comments on Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 -  
- Reopening Comment Period

The National Fisheries Institute (NFI) is pleased to submit comments to the Food and Drug Administration (FDA) on the Interim Final Rule, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), 69 Fed. Reg. 19763 (April 14, 2004) (Prior Notice Interim Final Rule).

The NFI is the national trade association for the diverse fish and seafood industry of the United States. The NFI's 700 members come from all sectors of the fish and seafood industry including fishing vessel owners, aquaculturalists, processors, importers, exporters, distributors, retailers, and restaurants. Since 1945, the NFI has been committed to providing consumers with ample, safe, sustainable, and diverse fish and seafood choices.

NFI and its members support the work of the Food and Drug Administration (FDA) and the Bureau of Customs and Border Protection (CBP) to provide food security for the U.S. food supply and wish to cooperate in assuring the new food security regulations, such as the submission of prior notice for imported food entries, are effectively implemented.

NFI is a member of the National Coalition of Food Importing Associations (NCFIA), which is also submitting comments to this docket. NFI has assisted in the development of and supports the comments submitted by the NCFIA. NFI appreciates the efforts of the FDA since the passage of the Bioterrorism Act to craft a workable scheme for the provision of prior notice to importation of food articles and its efforts on outreach and educational efforts concerning the new regulations.

NFI strongly supports the graduated enforcement policy that FDA wisely crafted and implemented and believes this policy has facilitated the transition into compliance with prior notice requirements. The first several months of prior notice implementation have provided an

opportunity for NFI and its members to observe the progress of FDA's prior notice system (PN). While the graduated enforcement policy has led to a mostly smooth transition, some issues and concerns have surfaced that demand attention and remediation.

The NCFIA letter identifies ten issues requiring the attention of FDA and CBP. The input provided to NFI from its member firms and others, such as customs brokers, involved in the seafood importing community validates the concerns raised in the NCFIA letter. A brief description of the ten items and associated recommendations follow. Please refer to the NCFIA letter for the necessary elaboration on each issue listed below.

The specific recommendations we request that FDA address include:

1. Creating an exemption for pre-purchase and trade samples imported for research/development purposes and laboratory and/or organoleptic analysis;
2. Resolving PN/Automated Broker Interface(ABI) system problems so that CBP entry and prior notice need not be made at the same time. Resolution of this timing problem is especially critical because for many foods, prior notice must be submitted before entry can be made (e.g., for quota class merchandise subject to CBP "live entry" requirements) and current system configurations can make it impossible to comply with both CBP and prior notice requirements.
3. Resolving PN/ABI system problems so that CBP entry can be made for articles of food that are already in the United States;<sup>1</sup>
4. Establish a system to communicate refusals and rejections to the importer, and to the ultimate consignee, if different, and to the electronic filer, if different, as well as the carrier;
5. Establish a system for swift resolution of technical and operational problems;
6. Establish a system that validates data and resolves conflicts between CBP and FDA databases;
7. Resolve the problem of duplicate prior notice filings;

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<sup>1</sup> We note that with several of the timing issues cited above, the issue arises because once Customs entry is made, the filer is locked out of the system altogether. De-linking these two systems so that Customs entry is no longer so closely tied to the prior notice may ease these problems.

8. Create provision for correction of errors in prior notice submissions, so long as corrections are made prior to passage of the 2, 4 or 8-hour deadline;
9. Improve the capacity of the FDA Prior Notice Internet System Interface; and
10. Continue to improve FDA communication to, and involvement with, the importing community.

All of the previously listed recommendations address important and valid concerns observed by our member firms, however, we wish to elaborate slightly on a few of the issues.

**Trade samples** are vital to the seafood industry because they allow U.S. firms to evaluate potential new overseas suppliers and products. These samples arrive in very small quantity and are used for internal evaluation purposes only. They are not distributed or sold for commercial purposes. An exemption from prior notice for trade samples, with the stipulations outlined in the NCFIA letter, is reasonable, workable and necessary to prevent an unnecessary hardship on the seafood industry.

**PN/Automated Broker Interface(ABI) system problems** can create glitches for fresh perishable seafood entries that could cause serious devaluation or loss of product. Although seafood is generally not classified as quota class merchandise for Customs purposes, we are interested in resolution of this problem (i.e. as described in item number two in the list above). Specifically, this issue is associated with the difference in regulatory timelines for prior notice versus CBP entry (i.e. the timing problem and connection between the CBP's ABI system and FDA's PN system). Seafood importers sourcing from points reachable by air in less than four hours may experience these problems due to the existing "wheels up" policy of CBP. While accounting for perhaps a minority of seafood entries, the problem creates serious challenges for the effected products and the importers and brokers handling these items. If a refusal occurs due to the incompatibility problem between the FDA and CBP systems, perishable fish shipments, which are typical of air cargo entries, could be devalued or destroyed by delays in refrigeration at point of entry.

**Swift resolution and communication of refusals and other problems** is necessary. We strongly support the fourth recommendation of the NCFIA that FDA and CBP establish a system to inform importers and customs brokers when a refusal of an entry has occurred as a result of inadequate prior notice. The reasons for notifying importers and brokers, as outlined in the NCFIA letter, are compelling. We believe our member firms are typical of the responsible firms in the food importing community who wish to know as soon as possible if a refusal occurs due to inadequate prior notice. As consignees, owners, etc. of the food, it is in the interest of food importers to quickly cooperate with the agencies to resolve inadequacies expeditiously. Carriers have considerably less interest in the matter and, in fairness to them, are not in a ready position to enact a correction or deal with the matter effectively.

**Regarding communications to the trade about errors in the filing of prior notices.** we believe the agencies must expand on their current outreach efforts. We note and appreciate that FDA recently issued and posted on its website a preliminary compliance report on prior notice. However, seafood importers attending a recent NFI Board meeting expressed a strong desire to receive timely and more detailed information about the types of errors and inadequacies the agencies are observing relative to the submission of prior notices. Moreover, our members are eager to know whether they are in compliance and, if not, in what way they are failing. Obviously, it is better to receive this information before the later and more serious enforcement stages of the enforcement policy begin.

**Allow the correction of errors in prior notice submissions** NFI strongly agrees with this recommendation as outlined in number eight of the list. We believe that there is no good reason not to allow the submission of revisions to a prior notice in FDA's PN system without having to fully cancel and re-submit a new notice. Human errors can and do occur in the filing process and information about the entries can change. Allowing changes without having to cancel the notice would make the process much less burdensome and will help to avoid the subsequent problems associated with cancellation of the original prior notices. Food security will not be compromised by such a change in procedure provided changes to the notices occur within established timelines.

**Expand communication and interaction with the trade** we urge FDA and CBP to create opportunities for expanded interaction with the trade. Affected food importers, brokers and trade associations are very interested in working with you to ensure the requirements are effective for food security purposes with as little disruption to commerce as possible. Regular communication is necessary to assure this objective is met.

Furthermore, we agree with NCFIA's recommendation that after full enforcement has been in place for at least 6 months, FDA should re-open the comment period for an additional 60 days. With the benefit of a period of active FDA/CBP enforcement and surveillance, the food import community will be better able to offer informed comments to FDA on the PN System. FDA will be in a better position to evaluate the degree to which the PN System is achieving its stated goals and any problems that have arisen. FDA should issue a final rule only after this period of full enforcement and additional comment.

Lastly, we agree with NCFIA's comments on the specific questions raised in FDA's *Federal Register* notice announcing the re-opening of the comment period, particularly the integration of CBP programs such as C-TPAT and FAST with the FDA PN requirements.

The National Fisheries Institute wishes to thank FDA for its efforts to create a workable Prior Notice System that balances food security needs and the realities of the import trade. Your efforts on outreach are appreciated including the opportunity to submit further comments

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concerning the interim final rule on prior notice. Please do not hesitate to contact us if you have any questions regarding these comments.

Sincerely yours,

Robert L. Collette  
V.P. of Science and Technology